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8 NESTLÉ WATERS NORTH AMERICA INC.

9 UNITED STATES DISTRICT COURT
10 CENTRAL DISTRICT OF CALIFORNIA
11 WESTERN DIVISION
12

13 CINDY BAKER, on behalf of herself
14 and all other similarly situated,

15 Plaintiff,

16 v.

17 NESTLÉ WATERS NORTH
18 AMERICA, a Delaware corporation, and
19 DOES 1 through 100, inclusive,
20 Defendants.

Case No. 2:18-cv-03097-VAP-PJW

DEFENDANT NESTLÉ WATERS
NORTH AMERICA INC.'S:

(1) NOTICE OF MOTION AND
MOTION TO DISMISS
PLAINTIFF'S FIRST AMENDED
COMPLAINT; AND

(2) MEMORANDUM OF POINTS
AND AUTHORITIES

[Request for Judicial Notice and
Declaration of Helene Lee Filed
Herewith]

Date: December 17, 2018

Time: 2:00 P.M.

Courtroom: 8A

Judge: Hon. Virginia A. Phillips

1 TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

2 PLEASE TAKE NOTICE that on December 17, 2018, at 2:00 p.m., or as
3 soon thereafter as counsel may be heard, before the Honorable Virginia A. Phillips,
4 in the United States District Court for the Central District of California, located at
5 350 W. First Street, Los Angeles, California, Courtroom 8A, defendant Nestlé
6 Waters North America Inc. (“Nestlé”) will and hereby does move to dismiss
7 plaintiff Cindy Baker’s first amended complaint.

8 Nestlé makes its motion on the grounds that, pursuant to Federal Rules of
9 Civil Procedure 8(a), 9(b), and 12(b)(6), plaintiff’s claims are barred based on
10 federal preemption, plaintiff fails to state a claim upon which relief may be granted,
11 and fails to plead her claims with particularity. Alternatively, Nestlé requests the
12 Court dismiss the action pursuant to the primary jurisdiction doctrine.

13 The motion is based on this notice, the memorandum of points and
14 authorities, the declaration of Helene Lee, the request for judicial notice, and all
15 pleadings, papers, and records on file in this action, and such other and further
16 evidence and argument of counsel as may be heard.

17 This motion is made following the conference of counsel, pursuant to Local
18 Rule 7-3, which Nestlé initiated on November 12, 2018.

19 Dated: November 19, 2018

WHITE & CASE LLP

21 By: /s/ Bryan A. Merryman
22 Bryan A. Merryman

23 Attorneys for Defendant
24 NESTLE WATERS NORTH
25 AMERICA INC.
26
27
28

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1 **I. INTRODUCTION**

2 Plaintiff Cindy Baker filed this lawsuit against Nestlé Waters North America
 3 Inc. (“Nestlé”), the manufacturer of Nestlé Pure Life® bottled water, based on news
 4 reports regarding a single discredited study that found “microplastic” particles¹ in
 5 all eleven brands of bottled water it tested, including Nestlé Pure Life®. Plaintiff
 6 alleges that Nestlé misled her and other consumers by using the words “purified”
 7 and “pure” on its Pure Life® labels because the water allegedly contains
 8 microplastic particles. But Pure Life® bottled water is in fact “purified water,” as
 9 the federal Food and Drug Administration (“FDA”) defines the term, and plaintiff
 10 does not allege otherwise. FDA, which has promulgated detailed regulations
 11 governing bottled water, expressly allows “purified water” manufacturers to use the
 12 words “purified” and “pure” on their labels, and does not require a disclosure
 13 concerning microplastic particles as plaintiff requests. Plaintiff’s state law claims
 14 based on the Pure Life® label are expressly preempted by 21 U.S.C. § 343-1, which
 15 bars states from imposing “any requirement” that is “not identical to” governing
 16 FDA requirements.

17 Plaintiff also fails to state a claim under the federal Magnuson-Moss
 18 Warranty Act (“MMWA”) because the MMWA does not apply to label statements
 19 governed by the federal Food, Drug, and Cosmetic Act (“FDCA”), and also because
 20 the label statements about which plaintiff complains are product descriptions, not
 21 warranties, and are thus not subject to the MMWA. Because plaintiff’s state law
 22 claims are preempted and amendment of her sole federal MMWA claim would be
 23 futile, the Court should dismiss the entire action with prejudice.

24 Additionally, plaintiff’s state law claims – each of which she bases on her
 25 personal opinion that “purified water” should not contain any microplastic particles,
 26 even though such particles are ubiquitous in the environment – are subject to

27
 28 ¹ Plaintiff defines “microplastics” as plastic particles, including polypropylene,
 nylon, and polyethylene terephthalate. FAC ¶ 7.

1 dismissal because plaintiff does not allege a factual basis on which this Court could
2 find “purified water,” as defined by FDA, may not contain microplastics.

3 Finally, in the alternative, the Court should dismiss the case without
4 prejudice under the primary jurisdiction doctrine to allow FDA to determine
5 whether “purified water” may contain microplastic particles.

6 **II. BACKGROUND**

7 Prior to commencing this lawsuit in April 2018,² plaintiff sent a demand
8 letter to Nestlé and other leading bottled water manufacturers. She contended that
9 several well-known brands of bottled water – among them, Nestlé Pure Life®
10 Purified Water (“Pure Life®”) – had been the subject of “a recent study conducted
11 at the State University of New York in Fredonia” that had revealed “unacceptable
12 amounts of plastic particles” in the water. FAC ¶¶ 35, 44; Request for Judicial
13 Notice (“RJN”) Ex. A.³ Specifically, plaintiff contended “[t]he study found that
14 some of the bottled brands ... contained pieces of microplastic, including
15 polypropylene, nylon, and polyethylene terephthalate.” RJN Ex. A. According to
16 plaintiff, the study thus established Nestlé Pure Life® bottled water was “not ‘pure’
17 or ‘purified’ as advertised and labeled by” Nestlé. *Id.*

18 The substantive allegations in the first amended complaint (“FAC”), which
19 names only Nestlé as a defendant, are essentially the same as the contentions in her
20 pre-suit demand letter. The crux of the FAC is:

- 21 • The State University of New York at Fredonia (“SUNY Fredonia”) has
22 conducted “[t]ests on more than 250 bottles [of water] from 11
23 brands,” including Pure Life®, which revealed the presence of “plastic

23 ² Plaintiff filed her original complaint on April 12, 2018; the Court dismissed the
24 action without prejudice for lack of service on August 16, 2018 (Docket No. 10);
25 the Court granted plaintiff’s motion to reopen the action on October 2, 2018
26 (Docket No. 12); plaintiff served Nestlé with a summons and copy of her original
complaint on October 15, 2018 (Docket No. 13); and plaintiff filed her first
amended complaint on October 29, 2018 (Docket No. 14).

27 ³ On a motion to dismiss, the Court may consider documents explicitly referenced
28 in a complaint without converting the motion to a motion for summary judgment.
See, e.g., Khoja v. Orexigen Therapeutics, Inc., 899 F.3d 988, 1002-03 (9th Cir.
2018) (explaining incorporation-by-reference doctrine).

particles” in the water. FAC ¶¶ 6, 8. Pure Life® was “found to contain ‘micro plastics’ such as polypropylene, nylon, and polyethylene terephthalate.” *Id.* ¶ 7.

- On October 31, 2017, plaintiff “purchased a case of Nestlé Pure Life® Purified bottled water for her and her family at the Smart & Final located in Encino, California,” which plaintiff and her family subsequently drank. *Id.* ¶¶ 1, 11.
- In light of the SUNY Fredonia study’s findings regarding the presence of microplastics in bottled water, the use of the words “pure” and/or “purified” on Pure Life’s® labels is misleading and misled plaintiff, who would not have purchased Pure Life® had she known there were microplastics in the water. *See id. generally.*

The FAC asserts eight claims for relief, each based on the allegation that Nestlé misrepresented the “purity” and/or “purification” of its Pure Life® branded bottled water: (1) violation of the MMWA, 15 U.S.C. §§ 2301 *et seq.*; (2) violation of California’s Consumers Legal Remedies Act (“CLRA”), Cal. Civ. Code §§ 1750 *et seq.*; (3) violation of California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code §§ 17200 *et seq.*; (4) breach of express warranty; (5) violation of California’s False Advertising Law (“FAL”), Cal. Bus. & Prof. Code §§ 17500 *et seq.*; (6) fraud; (7) negligent misrepresentation; and (8) injunction.

III. LEGAL STANDARDS

“Dismissal under Rule 12(b)(6) is proper when the complaint either (1) lacks a cognizable legal theory or (2) fails to allege sufficient facts to support a cognizable legal theory.” *Somers v. Apple, Inc.*, 729 F.3d 953, 959 (9th Cir. 2013). “To survive a motion to dismiss, a complaint must contain sufficient factual matter . . . to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Courts must disregard allegations that are legal conclusions, even when disguised as facts. *See id.* at 681.

Rule 9(b) governs fraud-based allegations. “Rule 9(b) demands that, when

1 averments of fraud are made, the circumstances constituting the alleged fraud be
 2 specific enough to give defendants notice of the particular misconduct so that they
 3 can defend against the charge[.]” *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097,
 4 1106 (9th Cir. 2003) (citations omitted). In other words, “[a]verments of fraud
 5 must be accompanied by ‘the who, what, when, where, and how’ of the misconduct
 6 charged.” *Vess*, 317 F.3d at 1106.

7 Dismissal without leave to amend is appropriate where “the pleading could
 8 not possibly be cured by the allegation of other facts.” *Ebner*, 838 F.3d at 963.

9 **IV. FEDERAL PREEMPTION BARS PLAINTIFF’S STATE LAW**
 10 **CLAIMS**

11 The Constitution’s Supremacy Clause provides that federal law is the
 12 “supreme Law of the Land ... any Thing in the Constitution or Laws of any State to
 13 the Contrary notwithstanding.” U.S. Const., Art. VI, cl. 2. In accordance with the
 14 Supremacy Clause, federal law can preempt state law either expressly – *i.e.*,
 15 through explicit preemption language in a federal statute – or impliedly. *See, e.g.*,
 16 *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1595 (2015) (explaining express and
 17 implied preemption).

18 **A. FDCA § 403A Expressly Preempts Plaintiff’s State Law Claims**

19 The FDCA “establishes basic definitions (known as ‘standards of identity’)
 20 for food products and prohibits the false labeling of such food products.” *Patane v.*
 21 *Nestlé Waters N. Am., Inc.*, 314 F. Supp. 3d 375, 378 (D. Conn. 2018). Congress
 22 has authorized FDA to “promulgate regulations fixing and establishing for any
 23 food, under its common or usual name so far as practicable, a reasonable definition
 24 and standard of identity....” 21 U.S.C. § 341; *see also In re Pepsico, Inc., Bottled*
 25 *Water Marketing & Sales Practices Litig.*, 588 F. Supp. 2d 527, 531 (S.D.N.Y.
 26 2008) (recognizing FDA’s authority to set “standards of identity”).

27 21 U.S.C. § 343-1 – often referred to as section 403A of the FDCA – is an
 28 express preemption provision that Congress enacted in connection with the federal

1 Nutrition Labeling and Education Act of 1990 (“NLEA”). *See Nemphos v. Nestlé*
 2 *Waters N. Am., Inc.*, 775 F.3d 616, 619-20 (4th Cir. 2015) (discussing the NLEA
 3 and section 403A). Section 403A provides, in pertinent part:

4 [N]o state or political subdivision of a state may directly or indirectly
 5 establish under any authority or continue in effect as to any food in
 6 interstate commerce --

7 (1) **any requirement** for a food which is the subject of a
 8 standard of identity established under section 341 of this title
 9 that is **not identical to** such standard of identity or that is not
 identical to section 343(g) of this title

10 21 U.S.C. §343-1(a)(1) (emphasis added).

11 “Any requirement” embraces obligations imposed through either state
 12 statutory or common law claims. *See, e.g., Riegel v. Medtronic, Inc.*, 552 U.S. 312,
 13 324 (2008) (“Absent other indication, reference to a State’s ‘requirements’ includes
 14 its common-law duties.”); *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 443
 15 (2005) (in the context of express preemption, “the term ‘requirements’ ... reaches
 16 beyond positive enactments, such as statutes and regulations, to embrace common-
 17 law duties”); *Nemphos*, 775 F.3d at 624 (“The term ‘requirement’ in the NLEA’s
 18 preemption provisions must be read broadly” and includes “common-law rules and
 19 duties from the judiciary.”).

20 The phrase “not identical to” broadly sweeps in for preemption eligibility any
 21 state law obligation in any way “beyond, or different from, what federal law
 22 requires.” *In re Pepsico*, 588 F. Supp. 2d at 532; *see also* 21 C.F.R. §
 23 100.1(c)(4)(i)-(ii) (state requirements are “not identical to” federal requirements,
 24 and thus eligible for preemption under section 403A, if they “[a]re not imposed by
 25 or contained in” or “differ from those specifically imposed by or contained in” a
 26 pertinent FDCA provision or FDA regulation); *Turek v. Gen. Mills, Inc.*, 662 F.3d
 27 423, 427 (7th Cir. 2011) (Posner, J.) (“Even if the disclaimers that plaintiff wants
 28

1 added would be consistent with the requirements imposed by the Food, Drug, and
2 Cosmetic Act, consistency is not the test [for preemption]; identity is.”).

3 With these provisions and definitions in mind, the key questions in the
4 section 403A express preemption analysis are: (1) “whether the duty imposed by
5 the relief which plaintiffs seek is ‘a requirement for a food which is the subject of a
6 standard of identity’”; and (2) “whether this duty ‘is identical’ to the labeling
7 requirements of the FDCA.” *Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 107
8 (D.D.C. 2006) (preemption bars state law claims against dairy companies premised
9 upon failure to include warnings about the risks of lactose intolerance on milk
10 labels, as there is an FDA standard of identity governing milk that does not require
11 such warnings); *see also In re Pepsico*, 588 F. Supp. 2d at 534 (analyzing express
12 preemption similarly). If both questions are answered affirmatively, as they are
13 here, plaintiff’s state law claims are preempted. *See, e.g., In re Pepsico*, 588 F.
14 Supp. 2d at 537; *Mills*, 441 F. Supp. 2d at 108-09.

15 **1. There is a Detailed Standard of Identity for Purified Water**

16 Plaintiff bases each of her claims on the central allegation that the labels of
17 Pure Life® contain the words “purified” and “pure,” and that the use of these terms
18 is misleading because a study allegedly found microplastics in the water. *See, e.g.,*
19 FAC ¶¶ 34, 42, 50, 63, 68, 80, 89.

20 *In re Pepsico* involved preempted state law claims alleging Pepsi had
21 misrepresented its Aquafina-branded bottled water as coming from a mountain
22 spring when it was really tap water. In holding preemption barred those claims, the
23 court noted FDA has set a “standard of identity for bottled water [that] establishes
24 definitions for several different types of bottled water, including ‘**purified water,**’
25 ‘artesian water,’ ‘ground water,’ ‘mineral water,’ and ‘spring water.’” 588 F. Supp.
26 2d at 531 (citing 21 C.F.R. § 165.110(a)) (emphasis added).

27 Relevant here, FDA defines “purified water” as:
28

1 The name of water that has been produced by distillation,
 2 reverse osmosis, or other suitable processes and that
 3 meets the definition of ‘purified water’ in the United
 4 States Pharmacopeia, 23d Revision, January 1, 1995 ...
 5 may be ‘purified water’ or ‘demineralized water.’

21 C.F.R. § 165.110(a)(2)(iv).

6 Within the same regulatory provision, FDA sets forth, in great detail,
 7 requirements for bottled water quality, including the precise allowable
 8 concentrations of dozens of “inorganic substances” (*e.g.*, arsenic, cyanide,
 9 mercury), “volatile organic chemicals” (*e.g.*, benzene, tetrachloroethylene, vinyl
 10 chloride), and “pesticides and other synthetic organic chemicals” (*e.g.*,
 11 benzopyrene, glyphosate, PCBs). *See* 21 C.F.R. § 165.110(b)(4). Within the same
 12 provision, FDA also prescribes methods for testing the concentration of the various
 13 substances upon which it has imposed limitations and requires bottled water that
 14 exceeds any of its various bacterial, turbidity, color, odor, chemical, and/or
 15 radioactivity limitations be labeled as such. *See* 21 C.F.R. §§ 165.110(b)(4), (c).
 16 This is all to say that bottled water – and “purified water” in particular – is subject
 17 to highly detailed federal standards of identity, quality, and labeling.

18 **2. Plaintiff’s Proposed Requirements are “Not Identical To”** **Federal Requirements**

19 Plaintiff seeks to impose liability upon Nestlé for two basic reasons: (1) Pure
 20 Life® labels contain the words “purified” and “pure”; and (2) Pure Life® labels do
 21 not affirmatively disclose the presence of microplastics. *See, e.g.*, FAC ¶¶ 34, 42,
 22 50, 63, 68, 80, 89. Below is an image of the Pure Life® label:⁴

23 ⁴ As noted in the accompanying declaration of Helene Lee (at ¶ 2, Ex. A), this is
 24 one of three similar labels for Pure Life® bottles used in the United States since at
 25 least October 2017, when plaintiff claims to have purchased Pure Life® water.
 26 Because the three labels do not differ in their use of the words “purified” and
 27 “pure,” Nestlé includes only one of the labels here. The Court may take judicial
 28 notice of the Pure Life® label because it forms the basis of plaintiff’s lawsuit and
 plaintiff references its content throughout the FAC. *See, e.g., Escobar v. Just Born*,
 2017 WL 5125740, at *2 (C.D. Cal. June 12, 2017) (taking judicial notice of
 pictures of products and their packaging in connection with motion to dismiss
 where the plaintiff did “not dispute the authenticity of the[] photographs and
 reference[d] the Products’ packaging extensively in her Complaint”) (collecting



“**Purified.**” Pure Life® labels contain the word “purified” because Pure Life® water *is* “purified water,” as 21 C.F.R. § 165.110(a)(2)(iv) defines the term. Plaintiff does not allege otherwise and could not allege otherwise – at least in a manner consistent with Rule 11.⁵

“**Pure.**” Pure Life® labels contain the word “pure” in three contexts: (1) “Pure Life®” – *i.e.*, the brand name of the bottled water; (2) the statement “Pure Life Begins now™”; and (3) “A future full of possibilities starts by drinking pure quality water.”

“[A]lthough the FDA has ‘discouraged’ the use of the term [‘pure’]..., it did so out of concern that consumers may be misled into believing that bottled water labeled as ‘pure’ meets the processing standards required by the standard of identity for purified water” – *e.g.*, if spring water or well water were labeled “pure.” *In re Pepsico*, 588 F. Supp. 2d at 538 (citing *Beverages: Bottled Water*, 60 Fed. Reg. 57,076, 57,079). “Consumers cannot be misled in that fashion here, because [Pure Life®] is purified water.” *Id.* “Thus, the ‘purity’ field” – *i.e.*, the potential to bring state claims based upon representations regarding purity – “is not open as to purified water...” *Id.*

cases).

⁵ If plaintiff were to allege Pure Life® does not meet FDA’s standard of identity for “purified water” because of the presence of microplastics, she would be asking the Court to believe Nestlé and the other leading bottled water manufacturers to whom she sent her pre-suit demand letter have been selling non-purified water as “purified” for many years without detection by FDA. Such an allegation, without factual support suggesting it might be true, would be implausible. *See, e.g., Ebner*, 838 F.3d at 963 (“Determining whether a complaint states a plausible claim for relief is ‘a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.’”) (quoting *Iqbal*, 556 U.S. at 679).

As to the words “purified” and “pure,” plaintiff seeks to prevent Nestlé from using terms FDA expressly permits (and, in the case of “purified,” requires when the product is in fact “purified water” (*see* 21 U.S.C. § 343(g)(2)), as it is here). This is a straightforward application of preemption. *See, e.g., Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1103 (N.D. Cal. 2012) (plaintiff’s state law mislabeling claims preempted where “the labeling challenged by [plaintiff] ... is expressly permitted by FDA regulations”); *Peviani v. Hostess Brands, Inc.*, 750 F. Supp. 2d 1111, 1119 (C.D. Cal. 2010) (state claims preempted where they “seek to enjoin the use of the very term permitted by the NLEA and its accompanying regulations”); *Dvora v. Gen. Mills*, 2011 WL 1897349, at *4 (C.D. Cal. May 16, 2011) (claims preempted where “Plaintiff apparently seeks to forbid General Mills from labeling its product ‘Total Blueberry Pomegranate,’ even though such descriptions ... are expressly authorized by federal law.”).

Absence of disclosures. To the extent plaintiff premises her claims upon the absence of affirmative disclosures concerning microplastics on Pure Life® labels, the law imposes no such requirements. *See* 21 C.F.R. § 165.110 *passim*.⁶ Because “[t]he warning requirement [plaintiff] seeks is simply not identical to FDA’s existing standard of identity[,] ... her failure-to-warn claim is preempted.” *Nemphos*, 775 F. 3d at 625 (state consumer protection law claims against bottled water companies based on failure to warn about dental fluorosis risks posed by

⁶ As discussed above, 21 C.F.R. § 165.110 prescribes the maximum allowable concentrations of dozens of chemicals and other substances in bottled water. “[M]icro plastics’ such as polypropylene, nylon, and polyethylene terephthalate” (FAC ¶ 7) are not among them. The same regulation also requires bottled water manufacturers to make certain disclosures on their labels: *e.g.*, to say the water is “from a community water system” or “from a municipal source” if it is publicly sourced and not purified water; to say it is “not sterile” if it is marketed toward infants and is not in fact sterile; or to say it contains more than the maximum allowable concentrations of the various regulated substances. 21 U.S.C. §§ 165.110(a)(3)(ii)-(iii); 165.110(c). It does not require bottled water manufacturers to include label disclosures concerning the presence of the microplastics, polypropylene, nylon, and/or polyethylene terephthalate plaintiff contends are present in Pure Life® and other popular bottled water brands.

1 fluoride in water expressly preempted under section 403A because “FDA’s
 2 standard of identity [*i.e.* 21 C.F.R. § 165.110] reaches warnings, and it does not
 3 demand a warning about dental fluorosis”); *see also Fisher v. Monster Bev. Corp.*,
 4 2013 WL 4804385, at *11 (C.D. Cal. July 9, 2013) (Phillips, J.) (claims preempted
 5 where “[p]laintiffs seek to impose an obligation to post certain warnings that are not
 6 imposed by the FDA”), *rev’d in part on other grounds*, 656 Fed. Appx. 819 (9th
 7 Cir. 2016); *Turek*, 662 F.3d 423 (“The disclaimers [regarding the presence of
 8 inulin] that the plaintiff wants added to the labeling of the defendants’ inulin-
 9 containing chewy bars are not identical to the labeling requirements imposed on
 10 such products by federal law, and so they are barred.”); *In re Pepsico*, 588 F. Supp.
 11 2d at 537 (state consumer protection law claims against purified bottled water
 12 manufacturer based on failure to disclose municipal source expressly preempted
 13 under section 403A because plaintiff sought to “impose requirements in addition,
 14 and not identical, to federal requirements”).

15 In sum, section 403A of the FDCA expressly preempts each of plaintiff’s
 16 state law claims because there is a federal standard of identity that governs the
 17 labels of bottles of “purified water” and plaintiff seeks to impose labeling
 18 requirements that are “not identical to” the governing federal requirements.⁷

19 ⁷ Plaintiff tries to frame her state law claims as based upon the violation of
 20 California’s Sherman Food, Drug, and Cosmetic Law, rather than the FDCA. *See*
 21 FAC ¶¶ 15-19. This is an effort to avoid preemption by 21 U.S.C. 337(a), which
 22 effectively prohibits individuals from suing for violations of the FDCA. *See, e.g.,*
 23 *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013); *Patane*, 314 F. Supp. 3d
 24 at 385. As already explained, plaintiff’s claims are expressly preempted under
 25 section 403A to the extent plaintiff attempts to impose requirements on Nestlé that
 26 are not identical to federal requirements. Together, sections 403A and 337(a)
 27 create a “‘narrow gap’ through which a state law claim must fit to escape
 28 preemption by the FDCA: ‘The plaintiff must be suing for conduct that *violates* the
 FDCA (or else [her] claim is expressly preempted by § [403A]), but the plaintiff
 must not be suing *because* the conduct violates the FDCA (such a claim would be
 impliedly preempted under [section 337(a)].’” *Perez*, 711 F.3d at 1120 (citing *In*
re Medtronic, Inc., 623 F.3d 1200, 1204 (8th Cir. 2010). In order to navigate this
 “narrow gap,” plaintiff must point to a state law: (1) Nestlé has violated through the
 use of the words “purified” and/or “pure,” and (2) that is identical to a
 corresponding provision of the FDCA or its implementing regulations. If plaintiff
 cannot do this (she cannot), her state law claims should be dismissed without leave
 to amend.

1 **V. PREEMPTION ASIDE, PLAINTIFF’S CLAIMS ARE NOT VIABLE**

2 **A. The Court Should Dismiss Plaintiff’s MMWA Claim**

3 Similar to her state law claims, plaintiff alleges that Nestlé violated the
4 MMWA by “provid[ing] a ‘written warranty’ ... for its bottled drinking water by
5 prominently affirming and promising in writing on the labeling of the bottled water
6 that they were ‘pure’ and ‘purified,’” and that Nestlé breached that warranty. FAC
7 ¶¶ 33, 34. The Court should dismiss this claim for two reasons.

8 First, the MMWA is “inapplicable to any written warranty the making or
9 content of which is otherwise governed by Federal law.” 15 U.S.C. § 2311(d). As
10 plaintiff alleges (FAC ¶ 15), the FDCA and its implementing regulations govern the
11 Pure Life® label content about which she complains. The MMWA thus does not
12 apply. *See, e.g., Mollicone v. Universal Handicraft, Inc.*, 2017 WL 440257, at *12
13 (C.D. Cal. Jan. 30, 2017) (“Where the FDCA governs the product at issue, a
14 plaintiff may not state a claim under the MMWA.”); *Hairston v. South Beach Bev.*
15 *Co.*, 2012 WL 1893818, at *5 (C.D. Cal. May 18, 2012) (same).

16 Second, the label content about which plaintiff complains – the words
17 “purified” and “pure” – are product descriptions, not warranties, and are therefore
18 not subject to the MMWA. *See, e.g., Hairston*, 2012 WL 1893818, at *6
19 (dismissing MMWA claim because the words “all natural with vitamins” ... are
20 ‘product descriptions’ rather than promises that Lifewater is defect-free, or
21 guarantees of specific performance levels”) (collecting cases); *Ogden v. Bumble*
22 *Bee Foods, LLC*, 2014 WL 27527, at *14 (N.D. Cal. Jan. 2, 2014) (“[T]his Court
23 and other courts in this district have repeatedly held that claims made on a food
24 product’s label are not ‘warranties’ within the meaning of the [MMWA] and thus
25 cannot serve as a basis for a [MMWA] claim.”) (collecting cases).

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B. Plaintiff's CLRA, UCL, and FAL Claims Fail on Multiple Grounds

The CLRA prohibits “unfair methods of competition and unfair or deceptive acts or practices.” Cal. Civ. Code §§ 1770(a). The UCL prohibits “any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising...” Cal. Bus. & Prof. Code § 17200. The FAL renders it “unlawful for any person ... with intent directly or indirectly ... to make or disseminate ... any statement, concerning ... real or personal property ... which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.” Cal. Bus. & Prof. Code § 17500.

1. The “Safe Harbor” Doctrine Bars These Claims

Plaintiff premises her CLRA, UCL, and FAL claims upon Nestlé’s allegedly misleading use of the words “purified” and “pure” on Pure Life® bottled water labels. *See* FAC ¶¶ 42, 50, 68. As discussed above, FDA authorizes the use of these terms on purified water labels (and plaintiff does not allege Pure Life® is not “purified water,” as defined by FDA). Such conduct thus falls within a “safe harbor” and cannot form the basis of a state consumer protection law claim. *See, e.g., Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 184 (1999) (pursuant to “safe harbor” doctrine, “courts may not use the unfair competition law to condemn actions the Legislature permits”); *Alvarez v. Chevron Corp.*, 656 F.3d 925, 933 (9th Cir. 2011) (affirming dismissal of UCL and CLRA claims where “California law unequivocally permit[ted] [d]efendants’ conduct”).

2. The Words “Purified” and “Pure” are Unlikely to Deceive a Reasonable Consumer

In the product mislabeling context, courts often evaluate CLRA, UCL, and FAL claims together, as each law demands, *inter alia*, a plaintiff plausibly allege the challenged label statements are likely to deceive a “reasonable consumer.” *See*,

1 *e.g., Williams v. Gerber Prods. Co.*, 552 F.3d 934, 938 (9th Cir. 2008); *Fisher v.*
 2 *Monster Bev. Corp.*, 656 Fed. Appx. 819, 822-23 (9th Cir. 2016); *Hairston*, 2012
 3 WL 1893818, at *4-5. The “reasonable consumer” standard requires a plaintiff to
 4 show the defendant’s representations regarding its product present “a likelihood of
 5 confounding an appreciable number of reasonably prudent purchasers exercising
 6 ordinary care.” *Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1026 (9th Cir.
 7 2008) (internal quotation marks and citations omitted). In other words, there must
 8 be “more than a mere possibility that the [label statement] might conceivably be
 9 misunderstood by some few consumers viewing it in an unreasonable manner.”
 10 *Lavie v. Procter & Gamble Co.*, 105 Cal. App. 4th 496, 508 (2003).

11 Because plaintiff’s CLRA, UCL, and FAL claims sound in fraud, they are
 12 subject to Rule 9(b)’s heightened pleading standard. *See, e.g., Vess*, 317 F.3d at
 13 1103-04 (Rule 9(b) applies to state law claims “grounded in fraud” or that “sound
 14 in fraud,” including CLRA, UCL, and FAL claims); *Brazil v. Dole Food Co.*, 935
 15 F. Supp. 2d 947, 963-65 (N.D. Cal. 2013) (analyzing CLRA, UCL, and FAL claims
 16 under Rule 9(b)). Among other requirements, Rule 9(b) demands a plaintiff “set
 17 forth what is false or misleading about a statement, ***and why it is false.***” *Vess*, 317
 18 F.3d at 1106 (quotation marks and citations omitted; emphasis added).

19 As already discussed, Pure Life® is in fact “purified water,” insofar as it is
 20 produced in the manner described in 21 C.F.R. § 165.110(a)(2)(iv), and plaintiff
 21 does not allege otherwise. As FDA and the court in *In re Pepsico* have recognized,
 22 the word “pure” is not deceptive when used to describe “purified water.” *See In re*
 23 *Pepsico*, 588 F. Supp. 2d at 538 (“Consumers cannot be misled [by the use of the
 24 word ‘pure’] here, as *Aquafina* is purified water.”) (citing *Beverages: Bottled*
 25 *Water*, 60 Fed. Reg. 57,076, 57,079).

26 Plaintiff’s allegations in the FAC clearly show her conception of the words
 27 “purified” and “pure” is divorced from the water purification process or FDA
 28 definitions and grounded more in her personal belief that “purified water” cannot

1 contain anything other than two parts hydrogen and one part oxygen. *See* FAC ¶ 11
 2 (“[B]ased on Defendant’s ‘pure’ and ‘purified’ representations on its water bottle
 3 labels, a reasonably prudent consumer would not expect Nestlé Pure Life® Purified
 4 drinking water to include synthetic or artificial ingredients, especially the
 5 potentially harmful plastics and micro plastics described herein.”). The
 6 reasonableness of her personal belief is undermined by FDA’s own recognition that
 7 bottled water may contain myriad “synthetic or artificial” substances (*e.g.*, arsenic,
 8 cyanide, carbofuran, PCBs) and still be safe for human consumption and properly
 9 labeled “purified water.” *See* 21 C.F.R. § 165.110(b) (setting forth standards of
 10 quality for bottled water).

11 Moreover, assuming the factual accuracy of plaintiff’s allegations (as the
 12 Court must at this stage), the reasonableness of her alleged belief is undermined by
 13 the facts that the SUNY Fredonia study revealed microplastic particles in all eleven
 14 brands of bottled water tested and that plaintiff threatened to sue the manufacturers
 15 of the five manufacturers of those brands of bottled water for the same reasons it
 16 now sues Nestlé. *See* FAC ¶ 8; RJN Ex. A. If all brands of bottled water contain
 17 microplastics, that fact confirms microplastics are virtually everywhere. For
 18 example, the air we breathe contains microplastics, as does tap water. Without
 19 providing any context regarding the prevalence of microplastics in our daily lives or
 20 whether it is possible to ensure “purified water” contains no microplastic particles,
 21 which plaintiff has not done, there is no basis to find reasonable plaintiff’s personal
 22 belief that “purified water,” as defined by FDA, cannot contain microplastics.
 23 Thus, plaintiff has not plausibly alleged the words “purified” or “pure” would
 24 mislead a reasonable Pure Life® purchaser. Her CLRA, UCL, and FAL claims
 25 thus fail.

26 **3. To the Extent Plaintiff Bases Her CLRA, UCL, and FAL**
 27 **Claims on Nondisclosure, they Fail**

28 While not entirely explicit in the FAC, plaintiff appears to base her CLRA,

UCL, FAL claims on both affirmative misrepresentation (*i.e.*, the words “purified” and “pure”) and non-disclosure (*i.e.*, no warning regarding microplastics) theories. *See* FAC ¶¶ 42, 50, 68, 70. In the consumer protection context, “California courts have generally rejected a broad obligation to disclose...” *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1141 (9th Cir. 2012). Instead, relying on the California court of appeal’s decision in *Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824 (2006), “California federal courts have generally ... [held] that a manufacturer’s duty to consumers is limited to its warranty obligations absent either an affirmative misrepresentation or a safety issue.” *Id.* (quotation marks, citations, and brackets omitted); *see also Daniel v. Ford Motor Co.*, 806 F.3d 1217, 1225-26 (9th Cir. 2015) (citing *Wilson* for the proposition that “an omission must pose safety concerns to be material”); *Gray v. Toyota Motor Sales, U.S.A., Inc.*, 554 Fed. Appx. 608, 609 (9th Cir. 2014) (“California law instructs that a manufacturer’s duty to consumers is limited to its warranty, unless a safety issue is present or there has been some affirmative misrepresentation.”).

As discussed above, the words “purified” and “pure” are not affirmative misrepresentations when used to describe “purified water.” Thus, to proceed with her CLRA, UCL, and FAL claims under a non-disclosure theory, plaintiff must allege the concealed matter – microplastics – presents a safety concern, and she must do so in a specific and particularized manner, in accordance with Rule 9(b). *See Benavides v. Kellogg Co.*, 2011 WL 13269720, at *5 (C.D. Cal. March 21, 2011) (in consumer protection lawsuit involving crackers recalled for potential Salmonella contamination, dismissing CLRA claim based on non-disclosure where complaint did not include particularized allegations of safety threat). The FAC is devoid of factual content suggesting the microplastic particles allegedly in Pure Life® and other well-known brands of bottled water are a threat to human safety.

The closest plaintiff comes to implicating a safety issue is in paragraph 10 of the FAC, where she alleges “[p]articles around 110 microns in size ... can be taken

1 into the body’s hepatic portal vein,” while particles “in the range of 20 microns ...
 2 in drinking water have been shown to enter the bloodstream before it lodges in the
 3 kidneys and liver...” FAC ¶ 10. Plaintiff does not plausibly allege the
 4 microplastics allegedly found in Pure Life® (which plaintiff does not allege to be
 5 any particular size) pose a safety risk and thus cannot state a claim under the
 6 CLRA, UCL, or FAL on a theory of non-disclosure. *See, e.g., Daugherty*, 144 Cal.
 7 App. 4th at 835-36 (finding plaintiff “alleged no facts that would establish
 8 [defendant] was ‘bound to disclose’ the defect” because “[t]he complaint [was]
 9 devoid of factual allegations showing any instance of physical injury or any safety
 10 concerns posed by the defect”).

11 Additionally, to proceed with CLRA, UCL, or FAL claims under a non-
 12 disclosure theory, plaintiff must plausibly allege Pure Life® contained microplastic
 13 particles in an amount Nestlé knew to be harmful when plaintiff made her purchase.
 14 *See, e.g., Wilson*, 668 F.3d at 1145-46 (explaining CLRA and UCL claims based on
 15 non-disclosure require “[p]laintiffs [to] show that HP was aware of the alleged
 16 defect at the time the Laptops were sold”); *Punian v. Gillette Co.*, 2015 WL
 17 4967535, at *9-10 (N.D. Cal. Aug. 20, 2015) (explaining plaintiff must plausibly
 18 allege defendant’s knowledge of defect at the time of the sale to avoid dismissal of
 19 CLRA, UCL, and FAL claims, and holding plaintiff’s allegation that “consumers
 20 [had] filed ‘numerous complaints’ [about the defect] with Defendants” was
 21 insufficient to establish knowledge). The FAC does not allege Nestlé knew of a
 22 potentially harmful level of microplastics in Pure Life® at the time she purchased
 23 Pure Life® water, or today.

24 **4. Plaintiff’s CLRA Claim Must Be Dismissed In Part**

25 Plaintiff, based on Civil Code sections 1770(a)(2), (4), (5), (7), and (9),
 26 alleges Nestlé has violated the CLRA. FAC ¶ 41. Even assuming the truth of
 27 plaintiff’s factual allegations, three of these CLRA provisions plainly do not apply.
 28 First, the FAC does not suggest Nestlé has “[m]isrepresent[ed] the source,

1 sponsorship, approval, or certification” of Pure Life® in violation of section
 2 1770(a)(2). Second, the FAC does not suggest Nestlé has “[u]s[ed] deceptive
 3 representations or designations of geographic origin” on Pure Life® labels in
 4 violation of section 1770(a)(4). Third, the FAC does not suggest Nestlé
 5 “advertis[ed] good or services with intent not to sell them as advertised” with
 6 respect to Pure Life® in violation of section 1770(a)(9). Accordingly, the Court
 7 should dismiss plaintiff’s CLRA claim insofar as she bases it on the violation of
 8 sections 1770(a)(2), (4), or (9) of the Civil Code.

9 **C. Plaintiff Fails to State a Breach of Express Warranty Claim**

10 Plaintiff alleges that she “formed a contract with Defendant at the time
 11 Plaintiff ... purchased Defendant’s bottled water based on the representation and
 12 warranties made by Defendant, including that Defendant’s water is ‘pure’ and
 13 ‘purified,’” and that “Defendant breached ... the express warranties ... by not
 14 providing its consumers with the bottled water they believed they were
 15 purchasing...” FAC ¶¶ 61, 64.

16 “To prevail on a breach of express warranty claim under California law, a
 17 plaintiff must prove: ‘(1) the seller’s statements constitute an affirmation of fact or
 18 promise or a description of the goods; (2) the statement was part of the basis of the
 19 bargain; and (3) *the warranty was breached.*” *In re ConAgra Foods, Inc.*, 90 F.
 20 Supp. 3d 919, 984 (C.D. Cal. 2015) (quotation marks and citations omitted;
 21 emphasis added). For the same reason she fails to allege the words “purified” or
 22 “pure” would mislead a reasonable consumer, plaintiff does not plausibly allege
 23 Nestlé breached a warranty: Assuming for present purposes that Pure Life® water
 24 contains microplastic particles, nothing in the FAC suggests “purified water”
 25 cannot contain microplastic particles. Because plaintiff does not plausibly allege a
 26 breach, her express warranty claim fails.

27 **D. Plaintiff Fails to Plead Fraud and Negligent Misrepresentation**

28 Plaintiff bases her fraud and negligent misrepresentation claims, like all of

her other claims, on the allegation that Pure Life® bottled water is not “‘pure’ and ‘purified’” as labeled. *See* FAC ¶¶ 80, 89. The fraud claim is governed by Rule 9(b), which requires, *inter alia*, a plaintiff to “set forth what is false or misleading about a statement, and why it is false.” *Vess*, 317 F.3d at 1106 (quotation marks and citations omitted). The negligent misrepresentation claim is arguably subject to the less rigorous Rule 8(a) pleading standard. *See, e.g., Woods v. Davol*, 2017 WL 3421973, at *6 (E.D. Cal. Aug. 8, 2017) (noting the Ninth Circuit has not resolved the issue, but a “growing trend of authority applies Rule 8, and not Rule 9(b), to a California law negligent misrepresentation claim”); *Sater v. Chrysler Group LLC*, 2015 WL 736273, at *11-12 (C.D. Cal. Feb. 20, 2015) (Phillips, J.) (applying Rule 8(a) to negligent misrepresentation claim). The pleading standard, however, is not dispositive here, as both fraud and negligent misrepresentation claims require plausible allegations that the defendant made a misrepresentation of material fact and that the plaintiff justifiably relied upon the misrepresentation. *See, e.g., Doe v. Gangland Prods.*, 730 F.3d 946, 960 (9th Cir. 2013) (setting forth elements of fraud); *Glenn K. Jackson Inc. v. Roe*, 273 F.3d 1192, 1200 n.2 (9th Cir. 2001) (setting forth elements of negligent misrepresentation). As discussed above, plaintiff does not allege Pure Life® is not in fact “purified water,” as defined by FDA, and does not plausibly allege the presence of microplastic particles renders “purified water” un-purified. Plaintiff’s fraud and negligent misrepresentation claims thus fail.

E. Injunction Is a Form of Relief, Not a Claim

Plaintiff’s eighth claim for relief (erroneously titled ninth claim for relief) is for an injunction. An injunction, however, is a remedy plaintiff seeks; it is not a substantive claim for relief in its own right. *See, e.g., Jensen v. Quality Loan Serv. Corp.*, 702 F. Supp. 2d 1183, 1201 (E.D. Cal. 2010) (since “[a]n injunction is a remedy, not a separate claim or cause of action,” “a separately pled claim or cause of action for injunctive relief is inappropriate”) (quotation marks and citations

omitted). The Court should dismiss this claim because it is a form of relief and not a claim.

VI. ALTERNATIVELY, THE COURT SHOULD DISMISS THE ACTION UNDER THE PRIMARY JURISDICTION DOCTRINE

In the event the Court does not dismiss all of plaintiff's claims on other grounds, it should dismiss this action under the primary jurisdiction doctrine to allow FDA to determine whether "purified water" may contain microplastic particles. "The primary jurisdiction doctrine allows courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue within the special competence of an administrative agency." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). "[T]he doctrine is a 'prudential' one, under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Id.* Dismissal under this doctrine is appropriate if a claim "requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency, and if protection of the integrity of a regulatory scheme dictates preliminary resort to the agency which administers the scheme." *Id.* (quotation marks and citations omitted).

Although "no fixed formula exists for applying the doctrine of primary jurisdiction," the Ninth Circuit has "traditionally examined" four factors: "(1) a need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Id.* at 1115 (quotation marks, citations, and brackets omitted). Here, FDA clearly has the authority to and does regulate bottled water contents and labeling. In the event the Court does not dismiss the FAC in its entirety on other grounds, it will be necessary to resolve

1 technical issues best resolved on a uniform, nationwide basis by FDA, the agency
 2 with the requisite scientific expertise, such as: (1) whether microplastics at some
 3 level are dangerous to human health; (2) if so, what level in bottled water is
 4 acceptable; (3) whether water FDA expressly requires be labeled “purified water”
 5 or “pure” may contain microplastics; and (4) whether bottled water manufacturers
 6 should be required to disclose on the label the presence of microplastics.

7 In *Tran v. Sioux Honey Ass’n, Coop.*, the plaintiff asserted CLRA, FAL, and
 8 UCL claims against the defendant honey manufacturer, alleging the label
 9 statements “Pure” and “100% Pure” were misleading due to the presence of
 10 glyphosate, “a synthetic chemical and herbicide,” in the honey. *Tran*, 2017 WL
 11 5587276, at *1 (C.D. Cal. Oct. 11, 2017). The plaintiff’s “complaint, although
 12 ostensibly about the meaning of the terms ‘Pure’ or ‘100% Pure,’ [was] really about
 13 what constitutes a safe level of glyphosate in honey.” *Id.* at *2. Additionally, “it
 14 [was] undisputed that no tolerance level ha[d] been set for glyphosate in honey and
 15 no labeling requirement exist[ed] with respect to glyphosate in honey either.” *Id.*
 16 Similarly, this lawsuit is really about what constitutes a safe level of microplastics
 17 in bottled water, and FDA has imposed no tolerance level or labeling requirement
 18 concerning microplastics in bottled water. In *Tran*, the court (Judge Staton) stayed
 19 the action under the primary jurisdiction doctrine to give FDA “the opportunity to
 20 bring its expertise to bear on appropriate tolerance levels for glyphosate in honey
 21 and on labeling requirements regarding the same.” *Id.* at *3. In the event the Court
 22 does not dismiss the FAC in its entirety, it should dismiss this action to allow FDA
 23 the opportunity to evaluate tolerance levels and labeling requirements relating to
 24 microplastics in bottled water.

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1 **VII. CONCLUSION**

2 For the foregoing reasons, Nestlé respectfully requests the Court dismiss the
3 FAC with prejudice. Alternatively, Nestlé respectfully requests the Court dismiss
4 this action pursuant to the primary jurisdiction doctrine.

5 Dated: November 19, 2018

WHITE & CASE LLP

7 By: /s/ Bryan A. Merryman
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